

**REMARKS**

Claims 1-44 were pending. Claim 18 is cancelled and new claim 45 is added in the present amendment and is dependent on claim 1. Support for new claim 45 is found in the specification, for example, at page 35, lines 7 (“A sacrificial oxide technique was used to fabricate arrays of 1 mm x 1 mm silicon membranes with 10-100 nm x 45 μm slit pores”). As such claims 1-17 and 19-45 are pending. Applicants note that all amendments of claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the amended claims (or similar claims) in the future. Each of the objections and rejections in the pending Office Action is addressed in turn below. Applicants note that the typographical error in claim 7 has been corrected as suggested by the Examiner.

**I. The Claims Are Definite**

The Examiner has rejected claims 36-44 as being indefinite for reciting the term “said membrane” without proper antecedent basis. Applicants have amended claim 36 to replace the phrase “said membrane” with the phrase “said textured surface,” which finds antecedent support in claim 36, section (d).

**II. The Claims Are Novel And Non-obvious**

Claims 1-4, 7 and 8 have been rejected as allegedly lacking novelty in view of Keller (U.S. Pat. No. 5,948,255). Claims 13, 17-19 and 21 are rejected as allegedly being obvious in view of Keller and Van Rijn (U.S. Pat. No. 5,753,014). Applicants address these rejections together in view of the presently amended claims.

Keller describes a thin film particle filter and methods of making the filter. Keller does not describe or suggest use of filters in ultrafiltration systems or devices that are

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

configured for ultrafiltration of biological fluids received and returned to a subject vasculature. In particular, Keller does not teach or suggest systems or devices having a fluid delivery passageway configured to receive blood or plasma from a subject's vasculature, deliver the blood or plasma across the membrane to generate an ultrafiltered fluid, and deliver the ultrafiltered fluid and/or the blood or plasma to the subject's vasculature. Nor does Keller teach or suggest that the described filters are useful or usable for ultrafiltration of such biological fluids.

Applicants believe that the Van Rijn reference adds nothing to the teachings of Keller. In particular, there is no motivation to combine Van Rijn and Keller. The Examiner suggests adding the filters of Keller to the filter systems of Van Rijn. This is in direct contrast to the teachings of Van Rijn. The pores of Van Rijn are shown as being substantially circular, and thus not having the length and width dimensions of either the presently claimed invention or those aspects of Keller used in the Examiner's combination. Van Rijn specifically states that for filtration of blood components, long narrow pores are to be avoided.

The filter of the invention moreover appears to be highly bio-compatible. In this respect the invention is based on the recognition that a smooth membrane with a surface roughness much less than the pore size will prevent sticking of particles or cells on the membrane and in the perforations. This improves the biocompatibility and renders the filter of the invention applicable for vulnerable cell-cell separation techniques and other medical and bio-medical purposes. As such, good results were obtained with a specific embodiment of the invention in which the membrane as well as the inner surface of the pores have a surface roughness less than 100 nm, particularly less than 10 nm and in which the membrane has a thickness which is smaller than the average diameter of the pores. Such a membrane filter may be used for the separation of biological cells and is particularly useful if vulnerable particles or stress-sensitive cells should be separated with a high flow rate. Some cells, e.g. leucocytes, erythrocytes and blood platelets will show an enhanced stiffening of their cell-membrane whenever they enter narrow and long pores, and will stick inside these pores (leucocytes) or release their cell content (erythrocytes, blood platelets). The latter is avoided or at least counteracted by this specific embodiment of the membrane filter of the invention. Col. 2, lines 20-43 (emphasis added)

Thus, there is no basis for adding the Keller filters with the recited dimensions to the systems of Van Rijn. Even if combined, the combination of the two references does

not describe a device or system as claimed (e.g., does not provide an ultrafiltration system or device that are configured for ultrafiltration of biological fluids received and returned to a subject vasculature via a fluid delivery passageway configured to receive blood or plasma from a subject's vasculature, deliver the blood or plasma across the membrane to generate an ultrafiltered fluid, and deliver the ultrafiltered fluid and/or blood or plasma to the subject's vasculature). As such, the rejections should be withdrawn.

### CONCLUSION

It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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